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Health Solutions

**Section 5: 510(k) Summary**

1. Submitted By:

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AUG 27 2010

Date Prepared: November 23, 2009

2. Trade Name: Decompression[1] of Choice (DOC) and AAAR 2K10 (referred to collectively as the "Devices" in this document)
Common Name: Power Traction Equipment
Classification Name: ITH, Power Traction Equipment, 21 CFR, Section 890-5900

3. Predicate Device Information:

The Devices are substantially equivalent to the Saunders Group 3D Active Trac. K001712 and Chattanooga Group Triton/Tru-Trac/Tx/Triton Dts Traction K053223.

4. Device Description:

The Devices are a non surgical traction or also called decompression[1] systems. It accurately controls tensions designed to relax Para spinal musculature and to allow distractive- traction forces to decompress inter vertebral spinal disk space. The Devices do this by creating a negative pressure in the disc due to the distractive forces and treatment protocols. Bulges or herniation are reduced back into the center or annular part of the disc. Fibroblasts then form a matrix over the protruded area to form a "seal" over the previously injured area.

The load cell constantly updates the user interface provided which controls a gear-motor/linear actuator to immediately and safely apply forces as determined by qualified healthcare personnel. The load cell feedback is also used to further verify and adjust traction forces allowing for variations in patient postures and outside influencing forces. This method of operation allows safe, continuous and smooth operation of the unit and proper comfortable and safe appliance of said forces to the patient.

An extensive manual of suggested treatment protocols and safety warnings is furnished to the end user.

5. Intended Use Statement:

The Decompression[1] of Choice (DOC) and AAAR 2K10 is a non invasive method of applying distractive forces to the spine through controlled tensions.

It is designed to apply decompression[1] forces to intervertebral discs.

The Decompression[1] of Choice (DOC) and AAAR 2K10 may be used for back pain, neck pain, herniated discs, protruding discs, degenerative disc disease, sciatica and posterior facet syndromes.

[1] Decompression is unloading due to distraction and positioning and/or as non-surgical in nature.

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6. Technological Characteristics Comparison Summary

The Devices and predicate device K001712 are similar in shape and can be divided into similar smaller sections. They have a base, elevation, cervical, thoracic, pelvic and a controls section. The base supports the lifting mechanism and also provides a stable surface during table operation. The elevation section lowers the table surface so it is easier to get on and off of the table. The elevation section also elevates so the operator is working in an ergonomically correct position. The cervical section applies distractive forces and is capable of P-A flexion for targeting. The thoracic section is stationary and provides a mounting place for the cervical and pelvic sections. The pelvic section applies distractive forces and is capable of P-A flexion and axial rotation for targeting. The controls sections move and monitor the table during treatment.

The Devices and predicate device K001712 use similar material and construction methods. They are constructed from structural steel that has been welded and bolted together. All of the steel has been coated with a protective coating to prevent rust. The cushions are constructed from plywood, foam and vinyl. The Plywood is the base of the cushion and mounts directly to the steel. The foam is secured to the plywood and provides a comfortable surface for the patient to lie on. Vinyl covers the foam and is secured to the plywood.

The Devices and predicate devices K001712 use different sources of power for the distractive forces. The Devices use a power supply and linear actuator to generate the force for distraction. The predicate device uses an air compressor and pneumatic cylinder. The force delivered to the patient is measured using a load cell, similar to a scale, and a plc interface for the devices. The predicate device uses an air pressure regulator and calculation to create the required force.

The Devices and predicate device K053223 perform similar traction pulls. Both the Devices and predicate K053223 have static, intermittent and cyclic ramp up, treatment and ramp down. They have similar hold period and rest period settings as well as ramp up and ramp down steps. The maximum traction of the predicate K053223 is 200 lbs. and the lumbar section of the devices is 200 lbs. The cervical section of the devices is limited to 50 lbs for safety of the patient.

7. Performance and Compliance Data

To prove the Devices are effective and as safe as the predicate performance testing was done on the cervical and lumbar sections. A calibrated scale was placed between the cervical and lumbar sections to simulate a patient. The scale was used to measure the force being applied to the patient. Using manual distraction the table was ramped up to target poundage and the readings where noted.

The Devices are in compliance with the following safety standards.

1. IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
2. IEC 60601-2-46, Medical Electrical Equipment; Part 2-46: Particular requirements for safety of Operating Tables, First Edition:1998
3. IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems, edition 1.1
4. UL 60601-1, Medical Electrical Equipment; Part 1: General Requirements for Safety, 1st Edition: 2003 with revisions dated April 26, 2006.
5. IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

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8. Biocompatibility Information

Materials that come in direct contact with the patient are the table top and cervical capture. The materials of those devices are used on marketed device with no known adverse effects. Because the materials are commonly used on other products biocompatibility testing is not warranted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Pivotal Health Solutions
% Intertek Testing Services NA, Inc.
Mr. William J. Sammons
2307 E. Aurora Road Unit B7
Twinsburg, OH 44087

AUG 27 2010

Re: K101889
Trade/Device Name: Decompression of Choice and AAAR 2K10
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: August 11, 2010
Received: August 13, 2010

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K101889

# Indications for Use

**510(k) Number:** K101889

**Device Name:** The Decompression[1] of Choice (DOC) and AAAR 2K10

**Indications For Use:**

The Decompression[1] of Choice (DOC) and AAAR 2K10 is a non invasive method of applying distractive forces to the spine through controlled tensions.

It is designed to apply decompression (decompression is unloading due to distraction and positioning and/or as non-surgical in nature) forces to intervertebral discs.

The Decompression[1] of Choice (DOC) and AAAR 2K10 may be used for back pain, neck pain, herniated discs, protruding discs, degenerative disc disease, sciatica and posterior facet syndromes.

[1] Decompression is unloading due to distraction and positioning and/or as non-surgical in nature.

| Prescription Use | X | OR | Over-The-Counter Use | |
|---|---|---|---|---|
| (Part 21 CFR 801 Subpart D) | | | (Part 21 CFR 801 Subpart C) | |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101889